



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 165

[Docket No. FDA-2018-N-1815]

RIN 0910-AI03

Beverages: Bottled Water

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to revise the quality standard for bottled water to specify that bottled water to which fluoride is added by the manufacturer may not contain fluoride in excess of 0.7 milligrams per liter (mg/L). This action, if finalized, will revise the current allowable levels for fluoride in domestically packaged and imported bottled water to which fluoride is added. We are taking this action to make the quality standard regulation for fluoride added to bottled water consistent with the recommendation by the U.S. Public Health Service (PHS) for community water systems that add fluoride for the prevention of dental caries. This action, if finalized, will not affect the allowable levels for fluoride in bottled water to which fluoride is not added by the manufacturer (such bottled water may contain fluoride from its source water).

DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows: Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions.")

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2018-N-1815 for “Beverages: Bottled Water.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in

accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Yinqing Ma, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2479.

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### I. Executive Summary

#### *A. Purpose of the Proposed Rule*

We propose to amend the allowable levels for fluoride in bottled water to which fluoride is added, to be consistent with the updated recommendation by the PHS on the optimal fluoride concentration in community water systems that add fluoride for the prevention of dental caries.

#### *B. Summary of the Major Provisions of the Proposed Rule*

The proposed rule would revise the quality standard for bottled water (found in § 165.110(b) (21 CFR 165.110(b)) to set the allowable level for fluoride at 0.7 mg/L in domestically packaged and imported bottled water to which fluoride has been added.

#### *C. Legal Authority*

We are proposing to update the quality standard for bottled water, as set forth in this proposed rule, consistent with our authority in sections 401, 403, and 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 341, 343, and 371). We discuss our legal authority in greater detail in section IV.

#### *D. Costs and Benefits*

The proposed rule, if finalized, would revise the quality standard regulations so that the allowable level for fluoride is 0.7 mg/L in bottled water to which fluoride has been added, to be consistent with the updated PHS recommendation on the optimal level of fluoride in community water systems that add fluoride for the prevention of dental caries. There would be one-time costs to learn the rule and one-time costs to verify the fluoride level after adjustment of the manufacturing process for bottled water manufacturers that choose to add fluoride to their products. The one-time costs range between \$129,802.42 and \$224,554.41. When discounted at seven percent over 10 years, the annualized costs range from \$18,480.94 and \$31,971.50. When discounted at three percent over 10 years the annualized costs range from \$15,216.80 and \$26,324.63.

#### II. Table of Abbreviations and Acronyms Commonly Used in This Document

Abbreviation/Acronym	What It Means
EO	Executive Order
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
HHS	Department of Health and Human Services
IBWA	International Bottled Water Association
PHS	U.S. Public Health Service

#### III. Background

##### *A. Need for the Regulation*

In 1973, FDA established standards of quality for bottled water, including allowable levels for fluoride, based on the PHS's 1962 Drinking Water Standards (38 FR 32558, November 26, 1973).

In adopting the 1962 PHS drinking water standard for fluoride, FDA concluded that the addition of fluoride to bottled water should be permitted to be consistent with the policy of allowing community water fluoridation (38 FR 32558 at 32561, November 26, 1973).

In 2015, the PHS updated and replaced its 1962 Drinking Water Standards related to community water fluoridation and recommended an optimal fluoride concentration of 0.7 mg/L. This recommendation is published in a *Federal Register* notice entitled “Public Health Service Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries” (80 FR 24936, May 1, 2015). In a 2011 notice proposing the revised fluoride recommendation, the Department of Health and Human Services (HHS) explained that the proposed update was based on the following information: (1) community water fluoridation is the most cost-effective method of delivering fluoride for the prevention of tooth decay; (2) in addition to drinking water, other sources of fluoride exposure have contributed to the prevention of dental caries and an increase in dental fluorosis prevalence; (3) significant caries prevention benefits can be achieved and risk of fluorosis can be reduced at 0.7 mg/L, the lowest concentration in the range of the then-current PHS recommendation; and (4) recent data do not show a convincing relationship between fluid intake and ambient air temperature and, therefore, there is no need for different recommendations for water fluoride concentrations in different temperature zones (76 FR 2383 at 2386, January 13, 2011).

FDA concludes that the basis for PHS’ updated recommendation of optimum fluoridation level of 0.7 mg/L in community water is a sound public health measure that should also apply to bottled water. Because bottled water is increasingly used in some households as a replacement for tap water, consumption patterns considered by EPA for community water can be used as an estimate for the maximum expected consumption of bottled water by some individuals. For

example, per capita consumption of bottled water in the U.S. increased from 29 gallons in 2007 to 42.1 gallons in 2017 (Ref. 1).

Therefore, FDA believes the allowable levels for fluoride in bottled water to which fluoride is added based on the PHS's 1962 Drinking Water Standards are outdated given the 2015 PHS updated recommendation (80 FR 24936, May 1, 2015). A regulation is needed to revise the FDA quality standard regulations so that the allowable level for fluoride is 0.7 mg/L in bottled water to which fluoride has been added. This level would be consistent with the updated PHS recommendation on the optimal level of fluoride in community water systems that add fluoride.

#### *B. FDA's Current Regulatory Framework*

Under the quality standard regulations for bottled water (§ 165.110(b)), we set different allowable levels for fluoride in bottled water depending on whether the water is bottled domestically or is imported, as well as on whether the fluoride in the bottled water is present in the source water or is added by the manufacturer. If a manufacturer adds fluoride to bottled water, then the allowable level for fluoride is governed by the regulation that applies to bottled water to which fluoride is added, regardless of whether some of the fluoride was present in the source water.

For bottled water that is packaged in the United States, we described two product types and for each established a range for the allowable levels for fluoride based on the annual average maximum daily air temperatures at the location where the bottled water is sold at retail. These temperature-related allowable levels were based on early data that suggested the amount of water (and consequently the amount of fluoride) ingested was influenced primarily by air temperature (38 FR 32558 at 32561). One range (1.4 to 2.4 mg/L) pertains to bottled water to which fluoride



is not added, and the other range (0.8 to 1.7 mg/L) pertains to bottled water to which fluoride is added. For imported bottled water, our standards are not temperature-dependent: there is a single allowable level for fluoride in bottled water to which fluoride is not added (1.4 mg/L), and a single allowable level for fluoride in bottled water to which fluoride is added (0.8 mg/L). When establishing the current allowable levels for fluoride, we explained that manufacturers of imported bottled water do not usually have direct control of the retail sale of their product. Therefore, by setting the allowable levels for imported bottled water at the lowest concentration in the range for each type of domestically bottled water (i.e., 1.4 mg/L for bottled water with no added fluoride and 0.8 mg/L for bottled water with added fluoride), imported bottled water may be sold in any location without exceeding the allowable fluoride levels of the drinking water standard (39 FR 32558 at 32561, November 26, 1973).

On April 27, 2015, we issued a letter to industry recommending, based on the updated PHS recommendation, that bottled water manufacturers not add fluoride to bottled water at concentrations greater than a final concentration of 0.7 mg/L (Ref. 2). In our letter, we also stated our intent to revise the allowable levels for fluoride in bottled water to which fluoride has been added to be consistent with the updated PHS recommendation. We did not receive any objections to the letter.

#### IV. Legal Authority

We are proposing to update the quality standard establishing the allowable levels for fluoride in bottled water to which fluoride has been added, as set forth in this proposed rule, consistent with our authority in sections 401, 403, and 701(a) of the FD&C Act.

Section 401 of the FD&C Act directs the Secretary of HHS (the Secretary) to issue regulations fixing and establishing for any food a reasonable definition and standard of identity,

quality, or fill of container whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers.

Under section 403(h)(1) of the FD&C Act, a food is misbranded if it purports to be or is represented as a food for which a standard of quality has been prescribed by regulations under section 401, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

Under section 701(a) of the FD&C Act, we may issue regulations for the efficient enforcement of the FD&C Act to “effectuate a congressional objective expressed elsewhere in the Act” (*Association of American Physicians and Surgeons, Inc. v. FDA*, 226 F. Supp. 2d 204 (D.D.C. 2002) (citing *Pharm. Mfrs. Ass’n v. FDA*, 484 F. Supp. 1179, 1183 (D. Del. 1980)).

Updating this allowable level for fluoride in bottled water to be consistent with the updated PHS recommendation would help effectuate the congressional objective expressed in sections 401 and 403 of the FD&C Act.

## V. Description of the Proposed Rule

We propose to revise the bottled water quality standard (§§ 165.110(b)(4)(ii)(C) and (D)) to be consistent with the updated PHS recommendation (80 FR 24936, May 1, 2015) by setting 0.7 mg/L as the allowable level for fluoride in bottled water to which fluoride is added. In addition, consistent with the updated PHS recommendation, we also propose to remove references to annual averages of maximum daily air temperatures in the current § 165.110(b)(4)(ii)(C), table 2; as discussed in the updated PHS recommendation, data do not show a convincing relationship between fluid intake and ambient air temperature (76 FR 2383 at 2386).

Therefore, the proposed rule would revise § 165.110(b)(4)(ii)(C) to specify bottled water packaged in the United States to which fluoride is added must not contain fluoride in excess of 0.7 mg/L. The proposed rule would revise § 165.110(b)(4)(ii)(C) by removing Table 2 and language pertaining to setting fluoride levels based on annual averages of maximum daily air temperatures. The proposed rule also would revise § 165.110(b)(4)(ii)(D) to specify that imported bottled water to which fluoride is added must not contain fluoride in excess of 0.7 mg/L. The proposed rule would not affect the allowable levels for fluoride in bottled water to which fluoride is not added by the manufacturer (but which may contain fluoride from its source water, specified in § 165.110(b)(4)(ii)(A) and (B)).

#### VI. Proposed Effective and/or Compliance Date(s)

We intend that any final rule resulting from this rulemaking would become effective 60 days after the date of the final rule's publication in the *Federal Register*. According to the International Bottled Water Association (IBWA), many of its member companies in the United States have already adjusted fluoride addition to obtain the 0.7 mg/L fluoride in their finished bottled water in response to the updated PHS recommendation and FDA's April 27, 2015, letter (Ref. 3). Therefore, we propose a compliance date 120 days after the effective date. We believe that the time frame for the compliance date is sufficient for bottled water manufactures to learn the rule and adjust their processes to bring their products into compliance with the new requirement.

#### VII. Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order (EO) 12866, EO 13563, EO 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). EO 12866 and EO 13563 direct us to assess all

costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). EO 13771 requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” This proposed rule is a significant regulatory action as defined by EO 12866. This proposed rule is expected to be an EO 13771 regulatory action. Details on the estimated costs of this proposed rule can be found in the rule’s economic analysis.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because updating the standards of the allowable level for fluoride in bottled water to which fluoride has been added specified in this proposed rule would not significantly increase costs to bottled water manufacturers, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$154 million, using the most current (2018) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full analysis of economic impacts is available in the docket for this proposed rule (Ref. 4) and at

<https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

### *Summary of Costs and Benefits*

The proposed rule would revise the standard for the allowable level for fluoride to 0.7 mg/L in bottled water to which fluoride has been added, a level consistent with the updated U.S. Public Health Service (PHS) recommendations for the optimal level of fluoride in community water systems to prevent dental caries (tooth decay). There may be some health benefits from revising this standard for fluoride in bottled water. As stated in the 2011 Department of Health and Human Services (HHS) notice proposing the revised recommended fluoride concentration, available data suggest that a concentration of 0.7 mg/L provides an optimal balance between the prevention of dental caries and the risk of dental fluorosis (76 FR 2383 at 2386). Moreover, this may reduce any unnecessary confusion on the part of consumers from having the standard for fluoride added to bottled water differ from the PHS recommendations for community water fluoridation.

There would be one-time costs to learn the rule for all bottled water manufacturers and one-time costs to verify the fluoride level after adjustment of the manufacturing process for bottled water manufacturers that choose to add fluoride to their product. The one-time costs range between \$129,802.42 and \$224,554.41. When discounted at seven percent over 10 years, the annualized costs range from \$18,480.94 and \$31,971.50. When discounted at three percent over 10 years the annualized costs range from \$15,216.80 and \$26,324.63. In Table 1, we provide the Regulatory Information Service Center and Office of Information and Regulatory

Affairs Consolidated Information System accounting information on the annualized costs and benefits of the proposed rule.

Table 1.--Economic Data: Costs and Benefits Statement

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized \$millions/year					7%		
						3%		
	Annualized Quantified					7%		
						3%		
	Qualitative	Update standard to make consistent with current PHS recommendations						
Costs	Annualized Monetized \$millions/year	\$0.025	\$0.018	\$0.032	2017	7%	10 years	
		\$0.021	\$0.015	\$0.026	2017	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized \$millions/year					7%		
						3%		
	Other Annualized Monetized \$millions/year	From:			To:			
						7%		
						3%		
		From:			To:			
Effects	State, Local or Tribal Government: No effect Small Business: No effect Wages: No estimated effect Growth: No estimated effect							

In table 2 we show a summary of the costs, cost savings and net costs. This proposed rule, if finalized, is considered an EO 13771 regulatory action.

Table 2.--EO 13771 Summary (in \$ Millions 2016 dollars) over an infinite time horizon

	Primary (7%)	Lower Bound (7%)	Upper Bound (7%)	Primary (3%)	Lower Bound (3%)	Upper Bound (3%)
Present Value of Costs	\$0.177	\$0.130	\$0.225	\$0.177	\$0.130	\$0.225
Present Value of Cost Savings	\$0	\$0	\$0	\$0	\$0	\$0
Present Value of Net Costs	\$0.177	\$0.130	\$0.225	\$0.177	\$0.130	\$0.225
Annualized Costs	\$0.0124	\$0.0091	\$0.0157	\$0.0053	\$0.0039	\$0.0067

Annualized Cost Savings	\$0	\$0	\$0	\$0	\$0	\$0
Annualized Net Costs	\$0.0124	\$0.0091	\$0.0157	\$0.0053	\$0.0039	\$0.0067

#### VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.32(m) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### IX. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

#### X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in EO 13132. We have determined that this rule has federalism impacts as it amends the standard of quality regulations for bottled water. The existing standard of quality is not new and already preempts state laws because it is within the scope of section 403A of the FD&C Act, an express preemption provision.

#### XI. Consultation and Coordination with Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in EO 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. We invite comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

#### XII. References

The following references are on display in the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. Rodwan, J.G. Jr., “Bottled Water. U.S. and International Developments & Statistics,” ([https://www.bottledwater.org/public/BMC2017\\_BWR\\_StatsArticle.pdf](https://www.bottledwater.org/public/BMC2017_BWR_StatsArticle.pdf)), *Bottled Water Reporter*, pp. 12-20, July/August, 2018.

2. FDA, “Letter to Manufacturers, Distributors, or Importers of Bottled Water with an Update on Fluoride Added to Bottled Water,” (<https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/bottledwatercarbonatedsoftdrinks/ucm444373.htm>), April 27, 2015

3. FDA Memorandum, “Teleconference Related to Fluoride in Bottled Water,” 2016.

4. FDA, “Proposed Rule to Revise the Allowable Level of Fluoride in Bottled Water to which Fluoride Has Been Added, Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis,” (<https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm> ).

List of Subjects in 21 CFR Part 165

Beverages, Bottled water, Food grades and standards, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 165 be amended as follows:



PART 165--BEVERAGES

1. The authority citation for part 165 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 343-1, 348, 349, 371, 379e.

2. Revise § 165.110(b)(4)(ii)(C) and (D) to read as follows:

§ 165.110 Bottled water.

\* \* \* \* \*

(b) \* \* \*

(4) \* \* \*

(ii) \* \* \*

(C) Bottled water packaged in the United States to which fluoride is added must not contain fluoride in excess of 0.7 milligram per liter.

(D) Imported bottled water to which fluoride is added must not contain fluoride in excess of 0.7 milligram per liter.

\* \* \* \* \*

Dated: March 26, 2019.

Scott Gottlieb,

Commissioner of Food and Drugs.

[FR Doc. 2019-06201 Filed: 4/2/2019 8:45 am; Publication Date: 4/3/2019]